



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94846d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7119
FAX: (612) 334-4142

June 28, 2004



WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 30

Craig E. Kosciolk
President
Craigador Corporation
5047 Clear Spring Drive
Minnetonka, Minnesota 55345

Dear Mr. Kosciolk:

On February 24, 2004, an investigator of the Food and Drug Administration conducted an inspection of your operation, "Craigador Corporation," as an own-label distributor. During the inspection the investigator collected labels for your "Lotus Restaurant" brand products. The label for your "Oriental Fried Rice" was collected from your contract manufacturer, 
 Our review of your firm's product labels reveals these products to be misbranded within the meaning of Sections 403(a)(1), 403(e)(1), and 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, Part 101--Food Labeling. These regulations may be found through links on our website at www.fda.gov.

The "Oriental Fried Rice," labeled under your product line "Lotus Restaurant™" for which you own the trademark, is misbranded within the meaning of Section 403(i)(2) of the Act in that it is fabricated from two or more ingredients but the label fails to bear the common or usual name of each ingredient in the product (21 CFR 101.4)

The "Oriental Fried Rice" is labeled with an ingredient listing as follows: "long rice, sweet peas, carrots, sweet corn, mushrooms, salad oil, oyster sauce, garlic, chicken flavor, sugar, salt." Our investigator observed that the label for the oyster sauce shows numerous ingredients not included on the "Oriental Fried Rice" label, including wheat flour and monosodium glutamate (MSG).

Wheat is a known allergen. Undeclared ingredients that are known allergens are of particular concern to the agency. FDA has received an increasing number of

Page Two

Craig E. Kosciolk
June 28, 2004

reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergic responses are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans, and derivatives of these products.

In addition, your label for fried rice states "NO MSG". However, oyster sauce is an ingredient of the oriental fried rice and its label identified that this sauce does contain monosodium glutamate (MSG). This causes the "Oriental Fried Rice" to be misbranded within the meaning of Section 403(a)(1) because it is false and misleading.

All labels are misbranded under 403(e)(1) in that they fail to bear the correct name and place of business of the manufacturer, packer or distributor. Your product labels identify the manufacturer as the [REDACTED] who is no longer an affiliate.

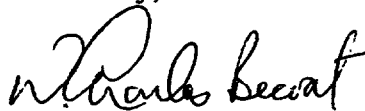
The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to ensure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

Failure to make prompt corrections may result in further enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and injunction against the manufacturer or distributor of illegal products.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations along with a copy of the revised label. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Compliance Officer Jane E. Nelson at the address indicated in the letterhead. Ms. Nelson can be reached at (612) 758-7119.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

JEN/ccl
CAH